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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,096	11/22/2000	Kimberly Christensen	98,541-C	4217

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MCDONNELL BOEHNEN HULBERT & BERGHOFF
300 SOUTH WACKER DRIVE
SUITE 3200
CHICAGO, IL 60606

EXAMINER

BEX, PATRICIA K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 04/16/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/721,096	CHRISTENSEN ET AL.	
	Examiner P. Kathryn Bex	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 February 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 47-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 47-58 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> .	6) <input type="checkbox"/> Other: _____ .

DETAILED ACTION

1. The cancellation of claims 59-74 is acknowledged and has been entered into the record.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 47-58 are rejected under 35 U.S.C. 102(b) as being anticipated by *Zhang et al* (WO 95/24498).

Zhang et al teach a method for removing wax-embedded (e.g. paraffin) sample from a slide by heating the slide in a temperature controlled bath operating at range of 5 to 50 Celsius degrees and flowing wash solution over the isolated specimen (page 11, line 11- page 12, lines 29). *Zhang et al* teach the wash solution comprising a buffer and a detergent. Wherein the detergent is non-ionic (page 12, lines 8-19). Note: the melting point of paraffin is between 50-57 degrees C, see instant specification (page 12, line 8). Therefore, the embedding medium (e.g. paraffin) is liquefied at its melting point (e.g. 50 degrees C). Moreover, the transitional term “comprising”, is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). “Comprising” is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct

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within the scope of the claim.); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948). The term “comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”, see MPEP 2111.03.

4. Claims 47-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Wang *et al* (USP 5,672,696).

Wang *et al* teach a method for removing paraffin-embedded specimen from a slide by heating the paraffin to 60 Celsius degrees or higher, then teach washing the isolated sample in a solution containing surfactant (column 2, lines 39-46). Note: the transitional term “comprising”, is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997).

5. Claims 47-50, 52-56, 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Key *et al* (USP 5,244,787).

Key *et al* teach a method for removing paraffin-embedded specimen from a slide by heating the paraffin at range of 55 to 60 Celsius degrees (depending of the type of paraffin). Key *et al* then teach placing the isolated sample into water or appropriate aqueous solution. The solution can contain ionic surfactants (column 5, line 40-column 6, line 33). Note: the transitional term “comprising”, is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997).

6. Claims 47-50, 52-56, 58 are rejected under 35 U.S.C. 102(b) as being anticipated by Muller *et al* (EP 508 568 A2).

Muller *et al* teach a method of removing paraffin wax-embedded sample from a slide by heating paraffin treated tissue sections to about 56 degree C, then the isolated specimen is washed in an buffered saline (e.g. non-organic liquid) (page 8, lines 41-47). Note: the melting point of paraffin is between 50-57 degrees C, see instant specification (page 12, line 8). Therefore, the embedding medium (e.g. paraffin) is liquefied at its melting point. Moreover, the transitional term “comprising”, is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.

Response to Arguments

7. Applicant's arguments submitted February 12, 2003 have been considered but have not been found persuasive. With respect to the rejection of claims 47-58 under 35 U.S.C. 102(b) as being anticipated by Zhang *et al* (WO 95/24498), Applicant argues that Zhang *et al* teaches methods which use organic solvents to dissolve paraffin at low temperatures. Examiner does not agree since Zhang *et al* also teaches another method for dewaxing utilizing a temperature control bath to more precisely control the required time for satisfactory dewaxing and decreasing processing time. The temperature bath operable to 50 degrees C. The melting point of paraffin is between 50-57 degrees C, see instant specification (page 12, line 8). Therefore, the embedding medium (e.g. paraffin) is liquefied at 50 degrees C.

In response to the rejection of claims 47-50, 52-56, 58 under 35 U.S.C. 102(b) as being anticipated by Key *et al* (USP 5,244,787), Applicant argues that Key *et al* is directed to an antigen retrieval method that is performed following sample deparaffinization. Applicant

appears to agree that Key *et al* do teach melting of the paraffin-embedded tissue. However, Applicant argues the remaining portions of the Key *et al* reference has nothing to do with deparaffinization. Examiner does not agree, since Key *et al* clearly teaches placing the isolated sample into water or appropriate aqueous solution, which clearly reads on the recited method steps. Moreover, the solution can contain ionic surfactants (column 5, line 40-column 6, line 33). Applicant is reminded the transitional term “comprising”, is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 47-58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,544, 798 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because, the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since both claim: a method of removing embedding medium from a biological sample, the method comprising the steps of: heating the embedding medium to at

temperature at or above the embedding medium's melting point and dispensing an immiscible fluid onto the biological sample. Additionally, if application is broader or more generic than the patent claim, the application is anticipated by the patent claim, see *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

Conclusion

10. No claims allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is (703) 306-5697. The examiner can normally be reached on Mondays-Thursdays, alternate Fridays from 6:00 am to 3:30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 308-4037.

The fax number for the organization where this application or proceeding is assigned is (703) 872-9310 for official papers prior to mailing of a Final Office Action. For after-Final Office Actions use (703) 872-9311. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.

Kathryn Bex
P. Kathryn Bex
Patent Examiner
AU 1743
April 14, 2003

Jill Warden
Jill Warden
Supervisory Patent Examiner
Technology Center 1700